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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,999	11/14/2003	Fumiyuki Shirai	245437US0	7356

22850 7590 09/26/2005

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
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ALEXANDRIA, VA 22314

EXAMINER

MORRIS, PATRICIA L

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,999	SHIRAI ET AL.	
	Examiner	Art Unit	
	Patricia L. Morris	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☒ Claim(s) 7 and 9-12 is/are objected to.
- 8) ☒ Claim(s) 1-6 and 8 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Election/Restriction

The variations in Y and $R^2 - R^5$ produce patentably distinct compounds capable of independent use.

This application has been found to contain more than one invention. Therefore, restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. The instances wherein Y is carbon and $R^2 - R^5$ represent non-heterocyclic groups, classified in class 548, subclass 366.1+
- II. The instances wherein Y is carbon and $R^2 - R^5$ is a heterocycle. classified in classes 540, 544, 546 and 548, various subclasses.
- III. The instances wherein Y is nitrogen and $R^2 - R^5$ represent non-heterocyclic groups, classified in class 546, subclass 275.4+.
- IV. The instances wherein Y is nitrogen and $R^2 - R^5$ is a heterocycle, classified in classes 540, 544 and 546, various subclasses.
- V. Claim 5, drawn to multiple processes, classified in classes 540, 544, 546 and 548, various subclasses.
- VI. Claim 8 drawn to multiple uses, classified in class 514, various subclasses.

Claims 7 and 9-12 are drawn to nonstatutory subject matter because they are drafted in terms of use. In the event that applicants amend the claims, they will be grouped accordingly.

These inventions are distinct, each from the other because of the following reasons:

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These distinct inventions have acquired separate status in the art, will support separate patents, and will require different fields of search for the respective inventions. Accordingly, restriction for examination purposes as indicated is considered proper; 35 U.S.C. 121; 37 CFR 1.141; 37 CFR 1.142.

Inventions I-IV are drawn to patentably distinct compounds.

A Markush-type claim is directed to A independent and distinct inventions if two or more of its members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In re Weber, 198 USPQ 330, footnote 3.

A reference to a pyrazine here would not be a reference to a piperidine. When one writes out the entire compound, as a whole, one arrives at patentably distinct heterocyclic compounds, along the lines indicated in the Groups of the first page of this action. Distinct, independent, heterocyclic nuclei.

Independent means the compound is capable of being utilized alone, not in combination with other compounds listed in the Markush expression; MPEP 802.01.

If the members are so diverse that they will support separate patents, *i.e.*, a reference for one would not constitute a reference for the other, then restriction is considered proper. MPEP 2173.05(h).

Inventions I-IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 3

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806.05(h)). In the instant case the products as claimed can be used in materially different processes as evidenced by applicants' own claims and specification.

Inventions I-IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products as made can be made by materially different processes as evidenced by applicants' own claims and specification.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

In the event of an election of either Groups I , II , III, IV or VI, applicants are required to elect a single disclosed species representative of the claimed invention since the variations in R^2 – R^5 encompass all heterocyclic chemistry classified in classes 540, 544 and 546, various subclasses. The staggering arrangement of possibilities does not permit classification of the claimed subject matter. Each heterocycle represents an independent and patentably distinct invention.

Should applicant(s) traverse on the ground that the species inventions identified are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the above identified species inventions to be obvious variants, or clearly admit on the record that this is the case. In either instance, of traverse, if the examiner finds one of the

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inventions in the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

Claims 1-4 and 6 will be examined to the extent readable on the elected compounds.

In the event of an election of Group VI, applicants are requested to elect a single disclosed method, i.e., a specific disease.

In the event of an election of Group V, applicants are requested to elect a single disclosed process.

In, In re Weber, 198 USPQ 332, In re Hengehold, 169 USPQ 473, was noted for the proposition that as long as applicants have maintained the right (as they do here) to file the non-elected subject matter in divisional applications, then restriction is proper, as to that point.

Applicant may file the divisional subject matter noted in divisional applications. If applicant wishes a generic expression of the elected invention the claims here need be amended to reflect that election.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

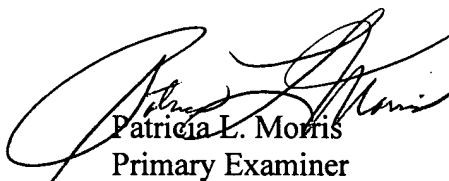
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688.

The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Patricia L. Morris
Primary Examiner
Art Unit 1625

plm

September 22, 2005